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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gary K. Michelson

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

12/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/593,591	Applicant(s) MICHELSON, GARY K.	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30/2009, 10/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7-20,22-30,32-44,46,47,49-86,88,89,91-129,148-164,166,168-184,186,188-204,206,208-224,226,228-264,266 and 268-300.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 43,44,46,47,49-84,153-157,183,184,186,188-202 and 243-262.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,155-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 and 268-300.

DETAILED ACTION

Election/Restrictions

Claims 43, 44, 46, 47, 49-84, 153, 154-157, 183, 184, 186, 188-202, and 243-244, 246, 248-262 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 26, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,155-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 and 268-300 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Upon further review of the present claim language, the Examiner determined that the present claims appear to contain new matter with respect to the original disclosure. In particular, the language in the independent claims such as:

- “maximum width transverse to the mid-longitudinal axis (e.g. claim 1, line 25);

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- “straight portions generally parallel to each other” (see e.g. claim 1, line 20);
- the “first dimension” and the “second dimension” and their relative lengths lacks original support and were not originally contemplated (see e.g. claim 1, lines 26-33);
- the bisecting plane passing through the opening (e.g. claim 1, lines 33-35)
- the trailing end non-linear portion between two parallel lines (e.g. claim 1, lines 33-37) was not originally contemplated. Merely referring to Figure 10 as the Applicant has proposed does not conclusively tell whether the Applicant originally contemplated the claimed details to the specificity that they are now set forth.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required: as an alternative to the Section 112, first paragraph new matter rejection set forth above, the Examiner assert that even if the claimed features were shown to have inherent support, they would at least lack any antecedent basis from the specification.

Claim Rejections Based Upon Prior Art

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7-12, 14, 16, 85, 86, 88, 89, 91-96, 98, 100, 102-105, 116, 117, 163, 164, 166, 168-173, 175, 179-180, 203, 204, 206, 208, 209, 211, 213, 215, 223, 224, 228-229, 231, 233, 235, 239, 240, 263, 264, 266, 268-269, 271, 273, 275, 279, and 280 are rejected under 35 U.S.C. 103(a) as obvious over Pafford et al (WO 98/17209) in view of Tienboon (US 5,861,041) or Gresser et al (WO 99/08627) or Tropiano (US 5,607,424). Pafford meets the claim language the bone ring as claimed is obtained from a long bone (see the paragraph bridging pages 12 and 13), the leading end as claimed is the posterior wall (115), and the trailing end is the anterior wall (111); see Figures 29 to 32. Upon inspection of Figure 29, it was not clear whether the opening is situated as called for in the present specification because the drawings are not drawn to scale. For this reason, Pafford is not considered meeting the limitation requiring the distance of first dimension being greater than the second dimension as claimed. However, Tienboon (see Figure 11) or Gresser (see Figure 1A) or Tropiano (see Figure 4) each suggest that it was known to make openings in spinal implants that are off center and closer to a leading edge than to a trailing edge. For this reason, it is the Examiner's position that it would have been obvious to make the Pafford implant with chamber closer to the "leading edge" for the same reasons that the prior art does

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the same. There is clearly no criticality for the claimed placement of the opening in the Applicant's device because the original specification says nothing about it. Moreover, the mere change in shape or aesthetic design has been held to be obvious absent some showing or evidence that such a change has a significant mechanical function; see MPEP sections 2144.04 I, IV that are incorporated herein by reference. It is further noted that there is no reason given for the location of the hole in the specification so it is considered obvious absent some persuasive evidence that such a particular configuration was significant; see *In re Daily*, 357 F.2d 669, 149 USPQ 47 (CCPA) 1966), and MPEP 2144.04 IV B.

Claims 1-2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, 280, 285, 288, 291, 294, 297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Tienboon (US 5,861,041) or Gresser et al (WO 99/08627) or Tropiano (US 5,607,424). Boyle discloses a bone ring obtained from a long bone (Figures 5, 10, 12, and column 2, lines 28-55) that has all the claimed structure except for non-arcuate upper and lower surfaces and the majority of the opening being towards the leading end as claimed. However, since Boyle teaches in other embodiments that it was known to utilize non-arcuate upper and lower surfaces (see Figures 1, 3, 9, 12, and 13), it is the Examiner's position that it would have been obvious to make the Figure 19 embodiment with non-

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arcuate upper and lower surfaces for the same reasons that Boyle utilizes the same in the other embodiments.

Additionally, Boyle does not disclose that the opening can have a majority of it between the leading end and the plane bisecting the length into two equal parts as claimed. However, Tienboon (see Figure 11) or Gresser (see Figure 1A) or Tropiano (see Figure 4) each suggest that it was known to make openings in spinal implants that are off center and closer to a leading edge than to a trailing edge. For this reason, it is the Examiner's position that it would have been at least obvious to make the Pafford implant with the opening closer to the "leading edge" for the same reasons that the prior art does the same. Moreover, the mere change in shape or aesthetic design has been held to be obvious absent some showing or evidence that such a change has a significant mechanical function; see MPEP sections 2144.04 I, IV that are incorporated herein by reference. It is further noted that there is no reason given for the location of the hole in the specification so it is considered obvious absent some persuasive evidence that such a particular configuration was significant; see *In re Daily*, 357 F.2d 669, 149 USPQ 47 (CCPA) 1966), and MPEP 2144.04 IV B.

Regarding claims 25 and 109, the plural openings are the pores in the bone that are naturally present in such material.

Claims 26-29, 110-113, 149-152, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149), Tienboon, Gresser, and Tropiano as used in the previous rejection, further in view of Kozak et al (US 5,397,364). Boyle

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fails to disclose the screw holes and screws as claimed. However, Kozak teaches that it was known to put multiple bone screws in similar implants as a means to secure them; see Figures 24 and 25 and the textual description of these figures. Therefore, it is the Examiner's position that it would have been obvious to use bone screws and have holes for them in the Boyle implant for the same reasons that Kozak uses the same: to secure the implant to the adjacent bone.

With regard to claims 28 and 29, it is the Examiner's position that it would have been prima facie obvious to make the bone screws and other bone implant components out of bone because the ring itself is made of that material. Since the ring itself is made of bone material, it would have been obvious to make the other parts of the implant out the same material because it would have all the advantages and purposes that led Boyle to make the bone ring out of bone or composites of bone.

Claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al, Tienboon, Gresser, and Tropiano as applied in the rejection of claim 1 above in further view of the suggestions of Boyle (US 6,277,149). Boyle et al fails to disclose the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been prima facie obvious over Boyle et al because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For

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this reason, it would have been prima facie obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

Claims 23, 24, 107, 108, 176, 216, 236, and 276 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al, Tienboon, Gresser, and Tropiano as applied against claim 1 above, further in view of Zdeblick et al (US 5,669,909). Boyle et al renders obvious the claim language as explained in the rejection of claim 1 above but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the Examiner's position that it would have been obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

Claims 283, 284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) in view of Tienboon (US 5,861,041). Boyle meets the rejection as explained in the rejection of claim 1 by Boyle *supra*, but fails to teach a generally oval shape or a greater width than length as claimed. However, Tienboon teaches that generally oval openings with width greater than lengths as claimed were known; see, e.g., Figure 11. Therefore, it is the Examiner's position that it would have been obvious to make the opening generally oval with a greater width than length as claimed for the same reasons that Tienboon does the same.

Response to Arguments

Applicant's arguments filed September 30, 2009 have been fully considered but were considered unpersuasive.

In traversing the Section 112, first paragraph rejection, the Applicant argues that the language "opposite sides generally parallel to each other" has original support. Upon further consideration, the Examiner decided that this language was not originally contemplated because what "generally parallel" means was not disclosed or described in the specification as originally filed. In particular the term "generally" adds a degree of breadth that was not originally disclosed and in a manner analogous to the manner in other modifying terms; see MPEP 2173.05 (b) F that is incorporated herein by reference thereto. Perhaps the Examiner should have rejected the claims under Section 112, second paragraph as well. The Examiner suggests deleting the phrase containing "generally parallel" in order to overcome the rejection with respect to this particular language.

The Applicant also argued that the language pertaining to the mid-longitudinal axis has original support. In response, the Examiner notes that a mid-longitudinal axis, by definition, runs along the length of the object it pertains. Therefore, a mid-longitudinal axis of Figure 10 would run vertically on the page that Figure 10 is located. For this reason, the Examiner cannot see how the Applicant can say that opening (114) has a maximum width transverse to a mid-longitudinal axis when it appears that the opening is actually wider along a mid-longitudinal axis not transverse to it. Furthermore, the Figures are not drawn to scale so one cannot utilize them to determine relative

dimensions; see MPEP 2125 under the heading "PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE" that is incorporated herein by reference. For this reason, the rejection has been maintained.

With regard to the other three bulleted items in the Section 112, first paragraph rejection, the Examiner asserts that they are based on proportions in the drawings and are not originally supported in Figure 10 or any other place in the specification.

In response to the traversal of the rejection utilizing Pafford (WO) in view of Tienboon (see page 4 of the response), the Examiner asserts that Tienboon was not utilized to teach the actual placement of the opening but to show that it was known to utilize off center openings. It is noted that the placement of the opening is not a critical feature of the invention because there is no discussion of it whatsoever in the Applicant's disclosure.

Likewise, the traversal of Gresser as not having a proper opening placement is misplaced because the secondary references were not utilized to show actual placement only that the concept of off center placement was known. Furthermore, the terms "leading" and "trailing" for the edges is based upon the intended use and manipulation of the device and not on actual structure. For this reason, one could call edge (15) of Gresser either the "leading" or "trailing" edge one desired to use it that way or to orient it in a manner that makes sense to the user. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

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the prior art. If the prior art structure is capable of performing the intended use, than it meets the claim.

The Applicant also traverses the use of Tropiano in the same manner as with Gresser and Tienboon. The same rationale is relevant to the equivalent teaching of Tropiano.

With regard to the rejections utilizing Boyle as a base reference, the Applicant relies on the same arguments as forwarded in the rejection utilizing Pafford (WO). For this reason, the Examiner considers the line of argument equally unpersuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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